**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 19-891/S-004
NDA 19-892/S-004

Abbott Laboratories
100 Abbott Park Road D
Abbott Park, IL 60064

22 AUG 2001

Attention: David Ross, Pharm. D., MBA
Associate Director, Regulatory Affairs

Dear Dr. Ross:

Please refer to your supplemental new drug applications dated March 31, 2000, received April 7, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dilaudid (hydromorphone hydrochloride, USP) Oral Liquid, 1 mg/mL (NDA 19-891), and Dilaudid (hydromorphone hydrochloride, USP), Tablets, 8 mg (NDA 19-892).

We acknowledge receipt of your submissions dated May 17, October 3, and November 9, 2000, and May 3, 2001.

These supplemental new drug applications provide revisions to the package insert including changing the Geriatric Use subsection as required by the Federal Register Notice of August 27, 1997 (62 FR 45313).

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text with the minor editorial revisions listed below.

1. In the WARNINGS section, "Hypotensive Effect" subsection, correct the parenthetical phrase to read "(see also PRECAUTIONS- Drug Interactions).

2. For NDA 19-891, in the SAFETY AND HANDLING INSTRUCTIONS section, first paragraph, at the end of the second sentence, add the word "cool" before the word "water" to read "…DILAUDID ORAL LIQUID should be treated by removal of any contaminated clothing and rinsing the affected area with cool water."

These supplemental applications are approved effective on the date of this letter

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted March 31, 2000), and include the agreed upon labeling for the Geriatric Use subsection as indicated in your fax dated May 3, 2001. These revisions are terms of the approval of these applications

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-891/S-004, 19-892/S-004." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research